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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/455,486	12/06/1999	DANIEL E. AFAR	1703-011.US2	5189

22462 7590 08/20/2002

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/20/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/455,486	Applicant(s) AFAR ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 June 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 08 July 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

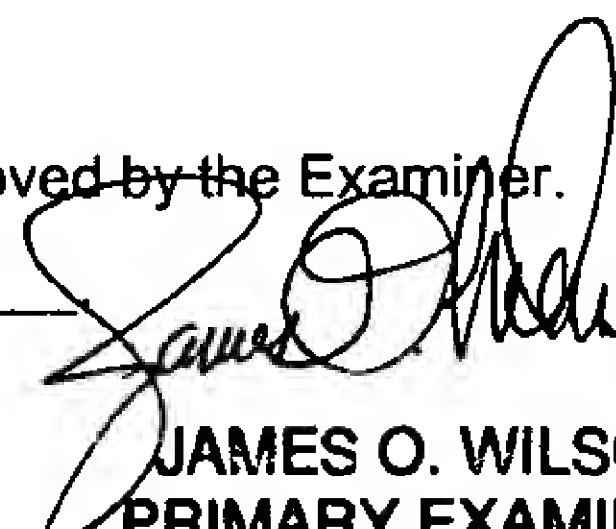
Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1 and 44-48.

Claim(s) withdrawn from consideration: 4-18, 20, 21 and 24-43.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: see attached.


JAMES O. WILSON
PRIMARY EXAMINER
Group 1600

Continuation of 2. NOTE: The suggested amendments will not be entered because the scope of the invention has been broadened to include an immunological response to all cancers and would require further considerations under 35 USC 112 first paragraph. The amendment would also invoke a new rejection under 35 USC 112, 2nd paragraph..

Advisory Action

Claims 1, and 44-48 remain rejected under 35 USC 112, 1st paragraph for the reasons of record in Paper No. 16, pages 3-5 and Paper No. 11, pages 6-11.

Applicant's declaration (Paper No. 21) has been considered in so far as it is recognized that the STEAP-2 protein is actually translated from the mRNA. However, such evidence does not obviate the rejections of record. In short, one of skill in the art would not know how to use the claimed invention with any predictability for the reasons of record. For example, with regards to a composition for the purposes of inducing an immunological response to prostate cancer, the specification provides no exemplification of or guidance on how to use the composition for immunotherapy in humans (see Paper No. 11, page 7, Item 1). Furthermore, with regards to the STEAP-2 polypeptide, there is no evidence that one of skill in the art would know how to use the invention as a diagnostic tool (Paper No. 11, page 9). The specification teaches (page 12, lines 9-14) that STEAP2 is expressed in both normal human prostate and prostate cancer. Furthermore, the declaration also recognizes that STEAP2 protein expression is predominantly specific in both normal prostate and certain types of prostate tumor cells (Declaration, page 2, Item 3). Thus, it would be unpredictable that STEAP2 protein expression would be useful for diagnostic and or prognostic purposes as the specification fails to differentiate a quantitative difference between cancerous and normal prostate tissue. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

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Claims 44, and 47-48 remain rejected under 35 USC 112, 1st paragraph for the reasons of record in Paper No. 16, pages 5-6. Applicant's response (Paper No. 20, page 4) is incomplete because certain statements have not been set forth.

The proper declaration should include the following:

I hereby certify, as applicant's undersigned attorney, that the deposit(s) listed on page # of the present application and having ATCC Designation No. #, were made pursuant to the Budapest Treaty on Month/Day/Year, and that all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed as of the issue date of the above-identified patent application as a patent, and that the deposits will be replaced if viable samples cannot be dispensed by the depository.

Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

All other objections are withdrawn in view of applicant's arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143.

The examiner can normally be reached on M-F, 8:30-5:00 P.M..

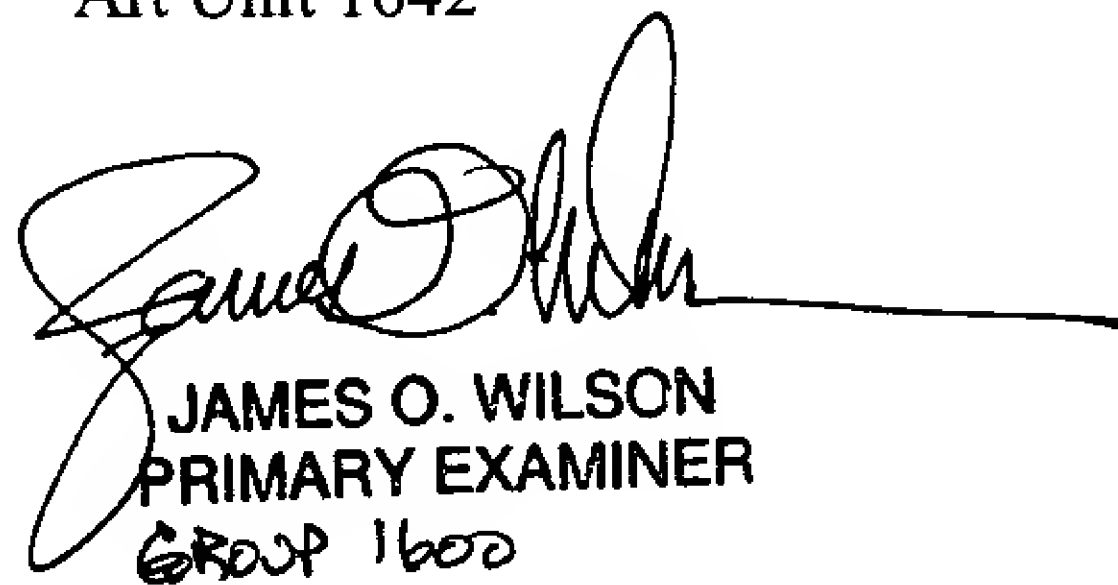
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 16, 2002



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600